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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,849	06/20/2003	Giovanni M. Pauletti	3715.12-1	8490

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EXAMINER	
SCHLIENTZ, NATHAN W	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,849	PAULETTI ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' Amendment and Election, with traverse, of: Invention II, encompassing claims 6-11; an anti-migraine drug, namely almotriptane, as the patentably distinct species and subspecies of drug; a hydrophilic carrier, namely polyethylene oxide, as the patentably distinct species and subspecies of carrier; hydroxypropyl methylcellulose as the patentably distinct species of mucoadhesive agent; ethoxydiglycol as the patentably distinct species of sorption promoter; film as the patentably distinct species of formulation; and a tampon or tampon-like device as the patentably distinct species of intravaginal device; which was filed on August 29, 2006, in response to the Official Action dated June 29, 2006, is acknowledged.

However, upon reconsideration, the aforementioned Restriction Requirement is vacated in favor of the following Restriction Requirement.

Status of Claims

Claims 1-5 and 17-20 were canceled, claims 6, 8-10 and 12-16 were amended, and claims 21-30 were added by the aforementioned Amendment. Because claims 1-5 and 17-20 were canceled in Applicants' response to the now vacated Restriction Requirement, the Examiner will consider original claims 1-5 and 17-20 to be currently pending and thus included, along with amended claims 6, 8-10 and 12-16 and newly added claims 21-30, within the new grouping of Inventions as set forth hereinbelow.

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 are drawn to a mucoadhesive composition comprising: either an anti-migraine drug or an anti-nausea drug; either a lipophilic carrier or a hydrophilic carrier; a mucoadhesive agent; and a sorption promoter, as classified in class 514, subclass 967.

II. Claims 6, 7, 9-11 and 21-30 are drawn to a method for treating either migraine and headache, or nausea and vomiting, *without the aid of an intravaginal delivery device*, wherein said method comprises intravaginally administering a formulation of said mucoadhesive composition, as classified in class 424, subclass 433.

III. Claims 8 and 12-16 are drawn to a method for treating either migraine and headache, or nausea and vomiting, *with the aid of an intravaginal delivery device*, wherein said method comprises intravaginally administering said intravaginal delivery device, which has a formulation of said mucoadhesive composition incorporated therein or coated thereon, as classified in class 424, subclass 431, and class 604, subclass 279.

IV. Claims 17-20 are drawn to an intravaginal device, as classified in class D03, subclass 203.5.

1. Inventions I and II are related as a product and a method of using said product *without the aid of an intravaginal delivery device*, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a product as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention II. For example, as opposed to administering said mucoadhesive composition intravaginally without the aid of an intravaginal

delivery device as claimed in Invention II, a formulation of said mucoadhesive composition may alternatively be administered sublingually as opposed to intravaginally, wherein said mucoadhesive composition may further comprise a diuretic to offset water retention (i.e., "bloating"), which is often associated with menstruation.

Inventions I and III are related as a product and a method of using said product *with the aid of an intravaginal delivery device*, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a product as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention III. For example, as opposed to intravaginally administering said mucoadhesive composition, which has been incorporated onto or within an intravaginal device as claimed in Invention III, a formulation of said mucoadhesive composition may alternatively be directly administered sublingually without the aid of a delivery device.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they have materially different designs, modes of operation, function, or effect. See MPEP §§ 802.01 and 806.06. In the instant case, the composition claimed in Invention I has a function and effect of treating either migraine and headache, or nausea and vomiting, whereas the device claimed in Invention IV has a design, mode of operation, and function for being inserted directly into the vagina. As a result, the composition claimed in Invention I has a materially different function and effect from the device claimed in Invention IV, and are therefore unrelated.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Invention II has a materially different mode of operation with respect to the method claimed in Invention III. More specifically, the method claimed in Invention II has a mode of operation of intravaginally administering a formulation of said mucoadhesive composition directly into the vagina *without the aid of an intravaginal delivery device*, whereas the method claimed in Invention III has a mode of operation that *requires the aid of an intravaginal delivery device* for intravaginally administering a formulation of said mucoadhesive composition into the vagina. As a result, the method claimed in Invention II has a materially different mode of operation from the method claimed in Invention III, and are therefore unrelated.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they have materially different designs, modes of operation, function, or effect. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Invention II has a mode of operation of intravaginally administering a formulation of said mucoadhesive composition directly into the vagina *without the aid of an intravaginal delivery device*, whereas the device claimed in Invention IV has a design, mode of operation, and function for being inserted directly into the vagina. As a result, the method claimed in Invention II has a materially different function and effect from the device claimed in Invention IV, and are therefore unrelated.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they have materially different designs, modes of operation, function, or effect. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Invention III has a mode of operation of intravaginally administering a formulation of said mucoadhesive composition directly into the vagina *with the aid of an intravaginal delivery device*, whereas the device claimed in Invention IV has a design, mode of

operation, and function for being inserted directly into the vagina. However, the device claimed in Invention IV need not necessarily comprise a mucoadhesive composition coated thereon or incorporated therein for the purpose of delivering a medicament, but may alternatively be utilized solely for the function and effect of absorbing physiological fluids. As a result, the method claimed in Invention III has a materially different function and effect from the device claimed in Invention IV, and are therefore unrelated.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden. As a result, restriction for examination purposes as indicated is proper. Applicants are therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

2. Claims 1, 3-6, 9-12, 15-17, 22-25 and 30 are generic to a plurality of disclosed patentably distinct species of drug, namely anti-migraine drugs and anti-nausea drugs, and subspecies thereof, such as ergotamine and metoclopramide, respectively. In addition, claims 1-3, 6, 17, 21, 22, 29 and 30 are generic to a plurality of disclosed patentably distinct species of carrier, namely lipophilic carriers and hydrophilic carriers, and subspecies thereof, such as a monoglyceride fatty acid having a C_8 to C_{18} chain, or a polyethylene glycol having a molecular weight between about 200 and 8000, respectively. In addition, claims 1-3, 6, 17, 21, 22, 27 and 30 are generic to a plurality of disclosed patentably distinct species of mucoadhesive agent (i.e., hydroxypropyl methylcellulose). In addition, claims 1-3, 6, 17, 21, 22, 28 and 30 are generic to a plurality of disclosed patentably distinct species of sorption promoter (i.e., ethoxydiglycol). In addition, claims 7, 8, 12, 17-20 and 26 are generic to a plurality of

disclosed patentably distinct species of formulation (i.e., cream). Furthermore, claims 8 and 12-20 are generic to a plurality of disclosed patentably distinct species of intravaginal device (i.e., tampon).

Even though this requirement is traversed, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of: 1. drug (i.e., an anti-migraine drug) and a subspecies thereof (i.e., ergotamine); 2. carrier (i.e., a lipophilic carrier) and a subspecies thereof (i.e., a monoglyceride fatty acid having a C_8 to C_{18} chain); 3. mucoadhesive agent (i.e., hydroxypropyl methylcellulose); 4. sorption promoter (i.e., ethoxydiglycol); 5. formulation (i.e., cream); and 6. intravaginal device (i.e., tampon); for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper. See MPEP § 808.01(a). In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicants should also include a chemical structure or a molecular formula of the elected compounds, if a chemical structure or a molecular formula of said compound is not already contained within the instant specification. If Applicants are unable to provide the chemical structure or the molecular formula of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

Conclusion to Restriction Requirement

The Examiner has required restriction between product and methods of using claims. Where Applicants elect claims directed to a product, and the product claim is subsequently found allowable, withdrawn methods of using that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of using

claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of using claims will be withdrawn, and the rejoined methods of using claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of using claims may be maintained. Withdrawn methods of using claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the methods of using claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of a single disclosed patentably distinct species of: 1. drug (i.e., an anti-migraine drug) and subspecies thereof (i.e., ergotamine); 2. carrier (i.e., a lipophilic carrier) and subspecies thereof (i.e., a monoglyceride fatty acid having a C_8 to C_{18} chain); 3. mucoadhesive agent (i.e., hydroxypropyl methylcellulose); 4. sorption promoter (i.e., ethoxydiglycol); 5. formulation (i.e., cream); and 6.

intravaginal device (i.e., tampon), that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an explicit election of a specific species and subspecies. See 37 C.F.R. § 1.143.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species and subspecies to be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, Applicants must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Due to the complex nature of the instant Restriction Requirement, a written restriction requirement was requested by the attorney of record, namely Ms. Hana Verny. See MPEP § 812.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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